Department of Labor and Industries
Office of the Medical Director
Health Technology Assessment Brief
Otto Bock Harmony Vacuum Assisted Socket System (VASS)

Company: Otto Bock/TEC

Product: The Harmony Socket Enhancement System includes a total surface bearing socket, Urethane interface/liner, sealing sleeves and a Harmony vacuum pump/shock absorber.

Purpose: Uses vacuum technology to:
1) maintain a balanced volume in an amputee's residual limb
2) minimize limb movement in the socket
3) facilitate perspiration evaporation within the socket
4) reduce friction between the limb, liner, and socket

FDA Status: Exempt because prosthetic devices are excluded.

Comparison: None. New technology.

Costs: $4000
HCPCS Code L5781 "Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system."

Insurers: Medicare reimburses $3150.08.
Aetna does not cover VASS.

LNI Cases: In 2002, 28 people underwent traumatic leg amputations, and 230 lower limb amputees received follow-up care.

Evidence: Funding for the two published studies came from TEC Interface, the manufacturer of the device.

Bell, TL, et al. "Interface pressures during ambulation using suction and vacuum-assisted prosthetic sockets." *J of Rehabilitation Research and Development.* 2002; 693-700.

Study Design	Primary Outcome	Inclusion	Exclusion	Baseline Pop Char	Blind	Results
Subject randomly began with normal or vacuum assisted condition and alternated until completed 3 trials of each condition. Subjects walked 20 m. Measurements taken after 5 steps to avoid acceleration. Measurements of residual limb to calculate leg geometry.	Measured average and peak pressure between skin and liner during stance. Measured average and peak air pressure during swing phase. Leg geometry.	Regular use of urethane liner and total surface weight bearing socket.	Vascular complications.	9 patients with mean age 46 years, mean limb maturity 18 years.	No	Peak pressure during stance were significantly lower with vacuum device. Average and peak pressure during swing were signifcantly greater with vacuum device.

Board, WJ, et al. "A comparison of trans-tibial amputee suction and vacuum socket conditions." *Prosthetics and Orthotics International.* 2001; 25: 202-209.

Study Design	Primary Outcome	Inclusion	Exclusion	Baseline Pop Char	Blind	Results
Comparison between normal and vacuum socket. Volume measurements taken before and after 30 minute walk on a treadmill. Subjects asked to normalize diet and activity levels.	Stump volume before and after 30-minute walk.	Transtibial amputee. No alcohol, caffeine, or exercise 24 hours before test.	Not reported.	10 unilateral, transtibial amputees, mean age 45 years, body mass 83 kg, height 1.67 m.	No	With the vacuum, stump volume increased significantly an average of 3.7%. In the normal condition, stump volume decreased 6.5%.